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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/670,046 | 09/24/2003 | Frank Hardt | RO0233US.CON (#90568) | 5022 |

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D. PETER HOCHBERG CO. L.P.A.
1940 EAST 6TH STREET
CLEVELAND, OH 44114

| EXAMINER | |
|---|---|
| DESAI, ANISH P | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1794 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/670,046 | HARDT ET AL. | |
| | Examiner | Art Unit | |
| | ANISH DESAI | 1794 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## *DETAILED ACTION*

1. In view of the Board's decision mailed on 02/17/09, PROSECUTION IS HEREBY REOPENED. New Ground(s) of rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

**A Technology Center Director or designee has approved this reopening of prosecution by signing below.**

/Gregory L Mills/

Acting Director of Technology Center 1700

## *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

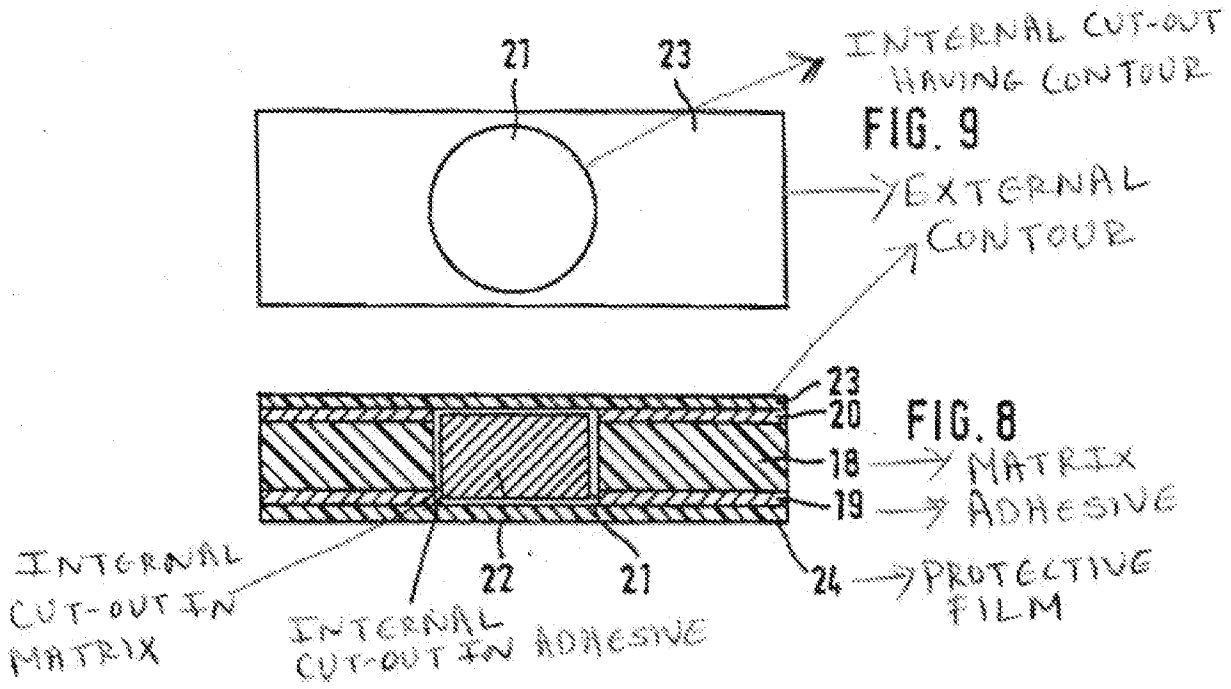
3. With respect to the claim recitation “gel-like”, it is submitted that the phrases such as "like" renders said recitation ambiguous because it is not clear as to what is meant by “gel-like”. As such the Examiner suggests deletion of “like”.

## *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreckel et al. (US 5,244,677) in view of Lindquist et al. (US 3,665,918) and Horstmann et al. (US 5,716,636), and as evidenced by Allen Jr. et al. (US 4,650,817).




5. With respect to claims 1 and 2, as set forth above in the Drawing reproduced from Kreckel, it is submitted that Kreckel discloses a transdermal drug delivery device (bandage strips) (equated to applicant's adhesive die-cut article) having a drug formulation that is stored in a punched out cavity of foam material such as polyethylene foam layer 18 (see abstract, column 6 lines 65-68 to column 7 lines 1-15). Additionally, as shown above in Figures 8 and 9 above, the adhesive die-cut article of Kreckel has an

external contour which comprises adhesive layer 19 with an internal cut-out having a contour, wherein the external contour of the adhesive die-cut article has no common point with the contour of the internal cut-out as claimed. Additionally, the die-cut article as set forth above in Figure 9 of Kreckel has a layer of foam 18 having punched out reservoir (equated to the matrix layer) having an internal cut-out which is congruent with the internal cut-out in the adhesive layer 19. Further, a protective film 24 (equated to covering film) (column 7 lines 10-15) covers the composite of matrix layer, adhesive layer, and the internal cut-out is provided in the article of Kreckel. With respect to claim 2, at column 5 lines 4-10, Kreckel discloses a polymeric film that is removably adhesively attached to one surface of Kreckel's device.

6. Additionally, at column 6 lines 67-68 to column 7 lines 1-5, Kreckel discloses "In FIGS. 8 and 9...for a transdermal delivery of low-viscous micro-emulsion [equated to applicant's filler material containing pharmaceutical active ingredient] containing the particular drugs. These micro-emulsions are contained in a material piece (22) of absorbent material placed in a punched out reservoir (21)…closed cells." This disclosure of Kreckel is interpreted to read on "wherein the internal cut-out is filled with filler material containing pharmaceutical active ingredient" as claimed.

7. Regarding claim 1, the difference between the claimed invention and the prior art of Kreckel is that Kreckel is silent as to teaching the foam layer (matrix layer) being a compacted material and specific pharmaceutical active ingredient as presently claimed.

8. However, Lindquist discloses a conformable adhesive sheet that has improved conformability and splitting resistance and can be used as surgical drape or bandage (abstract). The adhesive tape of Lindquist comprises compressed foam web (abstract). The compressed foam web of Lindquist is interpreted to meet claim requirement of "matrix layer being a compacted material" as presently claimed in claim 1. At column 2 lines 60-75 to column 3 lines 1-5, Lindquist provides motivation to use compressed foam (matrix layer being a compacted material). Specifically, Lindquist discloses that the use of compressed foam assures the presence of sufficient material to meet tensile strength requirement and still provides desired thinness of the web (column 2 lines 62-63). Additionally the disclosure of Lindquist at column 3 lines 1-25 with respect to the compression of foam is interpreted that such compression improves splitting resistance of the adhesive tape.

9. While it is noted that the disclosure of compression of foam in Lindquist's invention is primarily drawn to the polyurethane foam, whereas the primary reference of Kreckel discloses the use of polyethylene foam, the Examiner submits that at column 9 lines 55-65, Lindquist generally discloses that his inventive concept (i.e. compression of foam) has also applicability to functionally equivalent thermoplastic foams. The reference of Allen, Jr. et al. (US 4,650,817) is relied upon as an evidence to show that in adhesive bandage dressing art, polyethylene foam and polyurethane foams are functionally equivalent in formation of backing. Specifically, Allen discloses skin compatible adhesive composition that can be used in fabricating wound dressings

(abstract and column 1 lines 10-20). At column 10 lines 25-35, Allen discloses use of foam backing such as polyethylene or polyurethane as backing to form his adhesive tape.

10. It is noted that the primary reference of Kreckel discloses use of a matrix layer in formation of his/her adhesive tape, but Kreckel does not teach that the matrix layer being compacted material. Lindquist discloses adhesive tape that is useful in the same field as that of Kreckel, namely adhesive tape in medical field (e.g. as dressings). Further, Lindquist provides motivation to use compacted material, specifically the use of matrix layer being a compacted material provides sufficient tensile strength and also provides enhanced peel and splitting resistance (column 1 lines 10-15).

11. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the matrix layer of Kreckel as being compacted material, motivated by the desire to provide sufficient tensile strength and also provides enhanced peel and splitting resistance to the device of Kreckel.

12. Additionally, with respect to claim 1, Kreckel as modified by Lindquist is silent as to teaching the specific pharmaceutical active ingredient as presently claimed.

13. However, Horstmann discloses a transdermal therapeutic system comprising active substance acetylsalicylic acid (abstract).

14. It is noted that Kreckel as modified by Lindquist is silent as to teaching a specific drug. Therefore, based on the collective disclosure of Kreckel as modified by Lindquist and Horstmann, it would have been obvious to select the pharmaceutical active ingredient such as acetylsalicylic acid as taught by Horstmann and used in the invention of Kreckel, because selection of a known material based on its suitability for its intended use establishes *prima facie* obviousness.

15. With respect to claim 3, as shown in Figure 9 of Kreckel, the internal cut-out of Kreckel's device has a circular shape. Alternatively, regarding claims 3 and 4, there is no evidence made of the record that the particular shape of the internal cut-out is significant or is anything more than one of numerous shapes a person of ordinary skill in the art would find obvious for the purpose of providing a space for filling it with a filler material, therefore the shape of the internal cut-out in itself would not render the claims patentable over Kreckel (see *In re Dailey*, 149 USPQ 47 (CCPA 1976)).

16. With respect to claim 5, it would have been obvious to select the thickness of the adhesive layer and the matrix layer as presently claimed, motivated by the desire to provide the adhesive die-cut article having a suitable overall thickness so that it can be properly handled and applied to the skin of a person.

17. With respect to claim 6, the disclosure of Kreckel with respect to microemulsion (abstract) is interpreted to read on the filler material as being liquid as presently claimed.

18. With respect to claim 8, the matrix layer of Kreckel (i.e. foam) is formed of polyethylene (column 7 lines 1-5).

19. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kreckel et al. (US 5,244,677) in view of Lindquist et al. (US 3,665,918) and Horstmann et al. (US 5,716,636), and as evidenced by Allen Jr. et al. (US 4,650,817) as applied to claim 1 above, and further in view of Pfister et al. (US 5,232,702).

20. Kreckel as modified by Lindquist and Horstmann is silent as to teaching the specific adhesive as claimed in claim 7.

21. However, Pfister discloses a silicone pressure sensitive adhesive that is compatible with drugs, excipients, co-solvents and skin penetration enhancers (abstract). Additionally, the PSA of Pfister includes cohesive strengthening agent which helps to maintain the adhesive on the substrate, while reducing cold flow. The adhesive of Pfister is useful as an improved component in transdermal drug delivery devices and related medical devices (abstract).

22. It is noted that Kreckel's invention is in the field of transdermal delivery of drug (abstract). Further, Kreckel's invention discloses use of adhesive 19 in the transdermal drug delivery device. The PSA of the secondary reference of Pfister helps to maintain the adhesive on the substrate (e.g. skin), while reducing the cold flow.

23. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the silicone PSA of Pfister and used it in the invention of Kreckel, motivated by the desire to provide the adhesive that has improved cohesive strength and stability (abstract and column 1 lines 5-15 of Pfister).

***Response to Arguments***

24. Applicant's arguments filed in the appeal brief submitted on 12/29/06 have been fully considered but they are not persuasive. It is noted that the art rejection at issue in the appeal brief (i.e. the rejection under the 35 USC Section 103(a) based on Kreckel et al. (US 5,244,677) alone) is no longer relied upon by the Examiner in this Office action. However, since Kreckel et al. is still relied upon in this Office action as a prior art, the Examiner is rebutting applicant's arguments related to Kreckel et al. as applicable to the current art rejection of record.

25. On page 16 of the appeal brief, applicant argues that Kreckel neither suggests the use of a compacted material nor addresses the problem that certain drug will get in contact with unaffected skin. Therefore, Kreckel does not provide a suggestion as to the specific drugs which are set forth in present claim 1.

26. The Examiner agrees that Kreckel does not teach a compacted material. However, as set forth above in this Office action, the reference of Lindquist is relied upon to render applicant's claimed compacted material as being obvious. As to

applicant's arguments that Kreckel does not address the problem that certain drug will be in contact with unaffected skin, it is noted that said arguments are not commensurate in scope with the presently claimed invention. The Examiner reminds applicant that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir.1993).

27. Additionally, the Examiner submits that Kreckel generally discloses presence of drug in the device of his/her invention. Further, Kreckel's invention relates to transdermal drug delivery. Since Kreckel does not mention a specific drug including that of claimed by applicant, one of ordinary skill in the art would have to look for a suitable drug that can be used in Kreckel's invention. Hortsmann discloses transdermal therapeutic system which comprises a matrix having drug such as that of claimed by applicant (i.e. actylsalicylic acid) (see abstract).

28. Thus, it would have been obvious to select the pharmaceutical active ingredient such as acetylsalicylic acid as taught by Horstmann and used in the invention of Kreckel, because selection of a known material based on its suitability for its intended use establishes *prima facie* obviousness.

29. On page 16 of the appeal brief, applicant further argues "Moreover, Kreckel, et al. does not make the specific combination of a matrix made of a compacted material with a pharmaceutical active ingredient....present invention was made." In response, the Examiner submits, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.1986). The Examiner submits that as set forth in this Office action, the collective disclosure of Kreckel as modified by Lindquist and Hortsmann is relied upon to render the aforementioned combination as being obvious. Accordingly, applicant's arguments are not found persuasive.

***Conclusion***

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANISH DESAI whose telephone number is (571)272-6467. The examiner can normally be reached on Monday-Friday, 8:00AM-4:30PM.

31. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on 571-272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

32. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. D./
Examiner, Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794